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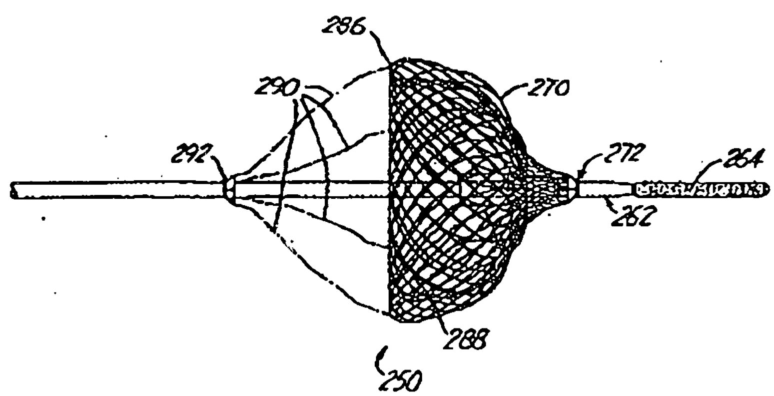


(57) Abstract

The present invention provides a method of forming a medical device and medical devices which can be formed in accordance with the method. In one embodiment, the method includes the steps of: a) providing a metal fabric formed of a plurality of strands formed of a metal which can be heat treated to substantially set a desired shape; b) deforming the metal fabric to generally conform to a surface of a molding element; c) heat treating the metal fabric in contact with the surface of the molding element to substantially set the shape of

the device can be allowed to elastically expand to substantially recover its thermally set, "remembered" shape from the heat treatment process, such as by urging the device distally to extend beyond the distal end of the catheter. This forward end 84 should be larger than the lumen of the shunt of the PDA.

The device can then be retracted so that the forward end 84 engages the wall of the pulmonary artery P. If one continues to retract the catheter, the engagement of the device with the wall of the pulmonary artery will tend to naturally pull the body portion 82 of the device from the catheter, which will permit the body portion to return to its expanded configuration. The body portion should be sized so that it will frictionally engage the lumen of the PDA's shunt. The device 80 will then be held in place by the combination of the friction between the body portion and the lumen of the shunt and the engagement between the wall of the pulmonary artery and the forward end 84 of the device. Over a relatively short period of time, thrombi will form in and on the device 80 and the thrombi will occlude the PDA. If so desired, the device may be coated with a suitable thrombolytic agent to speed up the occlusion of the PDA.

Figures 9A and 9B are a side view and an end view, respectively, of yet another embodiment of the present invention. This device 180 can be used for a variety of applications in a patient's blood vessels. For example, if a fabric having a relatively high pick (i.e. where the wire density is fairly great) is used in making the device, the device can be used to occlude blood vessels. In other applications, it may serve as a filter within a channel of a patient's body, either in a blood vessel or in another channel, such as in a urinary tract or biliary duct. In order to further enhance or reduce the device's tendency to occlude the vessel, depending on the application of the device a suitable known thrombogenic or antithrombogenic coating may be applied to the device.

This filter 180 has a generally conical configuration, tapering generally radially outwardly from its rearward end 182 to its forward end 184. A length of the device adjacent its forward end is adapted to engage the walls of a lumen of a channel. The maximum diameter of the filter device 180 is therefore at least as large as the inner diameter of the channel in which it is to be positioned so that at least the forward end

Having a series of unsecured ends 185 of the wire strands adjacent the forward end of the device will assist in seating the device in the channel because the ends of the wires will tend to dig into the vessel wall slightly as the forward end of the device urges itself toward its fully expanded configuration within the vessel. The combination of the friction between the outwardly urging forward end of the device and the tendency of the wire ends to dig into the vessel walls will help ensure that the device remains in place where it is deployed rather than floating freely within a vessel to reach an undesired location.

The method in which the device 180 of the invention is deployed may vary depending on the nature of the physiological condition to be treated. For example, in treating an arterio-venous fistula, the device may be carefully positioned, as described above, to occlude the flow of blood at a fairly specific location. In treating other conditions (e.g. an arterio-venous malformation), however, if may be desired to simply release a number of these devices upstream of the malformation in a vessel having a larger lumen and simply allow the devices to drift from the treatment site to lodge in smaller vessels downstream.

The decision as to whether the device 180 should be precisely positioned at an exact location within the channel in a patient's body or whether it is more desirable to allow the device(s) to float to their final lodging site will depend on the size of the channels involved and the specific condition to be treated. This decision should be left to the individual operator to be made on a case-by-case basis as his or her experience dictates; there is no one right or wrong way to deploy the device 180 without regard to the conditions at hand.

In the embodiment shown in Figures 9A and 9B, the wall of the device extends generally linearly from a position adjacent the clamp 90 and the other end of the device, approximating a conical shape. Due to the presence of the clamp 90, though, the end of the device immediately adjacent the clamp may deviate slightly from the cone shape, as indicated in the drawings. Alternatively, the wall may be curved so that the diameter of the device changes more rapidly adjacent the rearward end than it does adjacent its forward end, having an appearance more like a rotation of a parabola

The ends of the wire strands at the rearward end 182 of the device are secured with respect to one another, such as by means of a threaded clamp 90 such as that described above in connection with Figures 6A-6C. Portions of the wire strands adjacent the forward end 184 may also be secured against relative movement, such as by spot welding wires to one another where they cross adjacent the forward end. Such a spot weld is schematically illustrated at 186 in Figures 9A and 9B.

In the embodiment illustrated in Figures 9, though, the ends of the wire strands adjacent the forward end 184 in the finished device need not be affixed to one another in any fashion. These strands are held in a fixed position during the forming process to prevent the metal fabric from unraveling before it is made into a finished device. While the ends of the wire strands adjacent the forward end remain fixed relative to one another, they can be heat treated, as outlined above. The heat treatment will tend to fix the shapes of the wires in their deformed configuration wherein the device generally conforms to a molding surface of the molding element. When the device is removed from contact with the molding element, the wires will retain their shape and tend to remain intertwined. Accordingly, when the device is released from contact with the molding element, even if the ends of the wires are released from any constraint the device should still substantially retain its shape.

Figures 10A-10C illustrate three suitable molds for use in forming the filter 180 of Figures 9A and 9B. In Figure 10A, the molding element 200 is a single piece which defines a pair of generally conical portions abutting one another. In another similar embodiment (not shown), the molding element 200 may be generally ovoid, shaped not unlike an American football or a rugby ball. In the embodiment illustrated in Figure 10A, though, the molding element is a little bit less rounded. This molding element comprises two conical segments 202 which abut one another at their bases, defining a larger diameter at the middle 204 of the element which can taper relatively uniformly toward the ends 206 of the element 200.

When the a tubular braid is used in forming this device, the tubular metal fabric may be applied to the molding element by placing the molding element within the tubular braid and clamping the ends of the braid about the molding element before

may be rounded, as shown, rather than tapering to a sharper point at the ends of the molding element. In order to ensure that the braid more closely conforms to the outer surface of the molding element 200, i.e. the molding element's molding surface, the natural, relaxed diameter of the braid should be less than the maximum diameter of the element, which occurs at its middle 204. This will place the metal fabric in tension about the middle of the element and, in combination with the clamps at the ends of the braid, cause the braid to generally conform to the molding surface.

Figure 10B illustrates an alternative molding element 210 for forming a device substantially as shown in Figures 9A and 9B. Whereas the molding element 200 is intended to be received within a recess in the metal fabric, such as within the lumen of a length of tubular braid, the molding element 210 has an internal cavity 212 adapted to receive the fabric. In this embodiment, the molding element may comprise a pair of molding sections 214, 216 and these mold sections may be substantially identical in shape. Each of the molding sections 214, 216 generally comprise a conical inner surface 220 defined by a wall 222. Each section also may be provided with a generally cylindrical axial recess 224 for receiving a clamp 15 (or 90) carried by an end of the metal fabric.

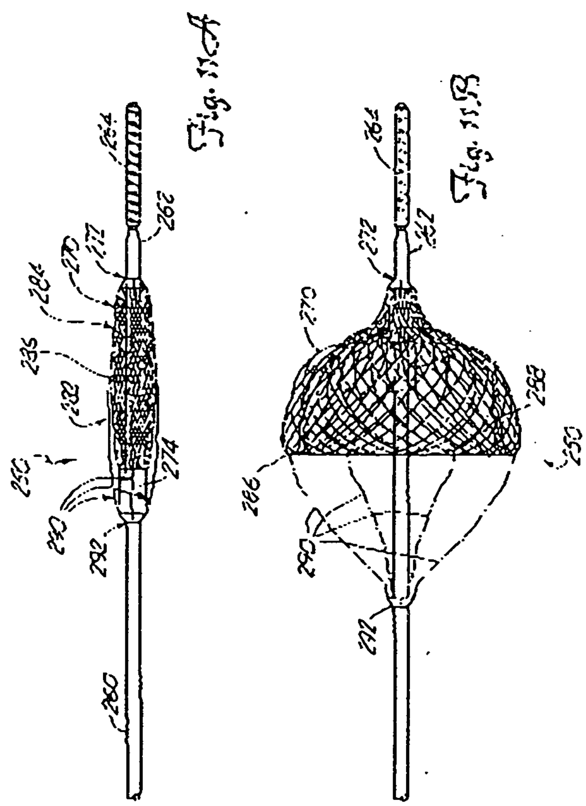
The two molding sections should be readily attached to one another with the larger, open ends 226 of the sections abutting one another. The mold sections can simply be clamped together, such as by providing a reusable jig (not shown) which can be used to properly position the sections 214, 216 with respect to one another. If so desired, bolt holes 228 or the like may be provided to allow a nut and bolt, or any similar attachment system, to be passed through the holes and attach the sections 214, 216 together.

In use, a suitably sized piece of a metal fabric, optimally a length of a tubular braid, is placed in the recess 212 of the molding element and the two molding sections 214, 216 are urged toward one another. The fabric should have a relaxed axial length longer than the axial length of the recess 212 so that bringing the sections toward one another will axially compress the fabric. This axial compression will tend to urge the wire strands of the braid radially outwardly away from the axis of the braid and

Once the metal fabric is deformed to generally conform to the molding surface of either molding element 200 or 210, the fabric can be heat treated to substantially set the shape of the fabric in its deformed state. If molding element 200 is used, it can then be removed from the interior of the metal fabric. If there is sufficient room between the resilient wire strands, the molding element can simply be removed by opening the web of wire strands and pulling the molding element out of the interior of the metal fabric. If molding element 210 is employed, the two molding sections 214, 216 can be moved away from one another and the molded fabric can be retrieved from the recess 212. Depending on the shape of the molding surface, the resulting formed shape may resemble either a pair of abutting hollow cones or, as noted above, a football, with clamps, welds or the like provided at either end of the shape.

This shape can then be cut into two halves by cutting the wires in a direction generally perpendicular to the shared axis of the cones (or the major axis of the ovoid shape) at a location about midway along its length. This will produce two separate filter devices 180 substantially as illustrated in Figures 9A and 9B. If the wires strands are to be joined adjacent the forward end of the device (such as by the weldments shown as 186 in Figures 9A and 9B), this can be done before the conical or ovoid shape is severed into two halves. Much the same net shape could be accomplished by cutting the metal fabric into halves while it is still carried about molding element 200. The separate halves having the desired shape could then be pulled apart from one another, leaving the molding element ready for forming additional devices.

In an alternative embodiment of this method, the molding element 200 is formed of a material selected to permit the molding element to be destroyed for removal from the interior of the metal fabric. For example, the molding element may be formed of a brittle or friable material, such as glass. Once the material has been heat treated in contact with the molding surface of the molding element, the molding element can be broken into smaller pieces which can be readily removed from within the metal fabric. If this material is glass, for example, the molding element and the metal fabric can be struck against a hard surface, causing the glass to shatter. The



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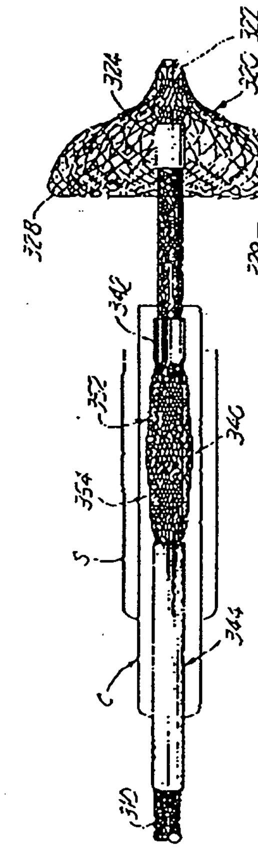

Fig. 14

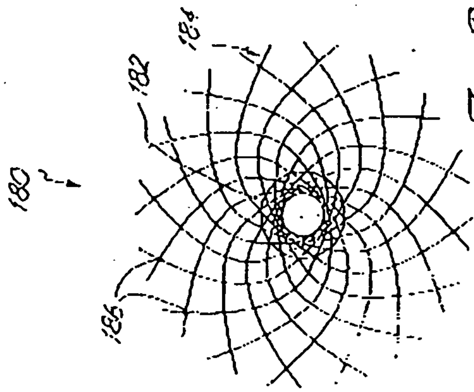

Fig. 9B

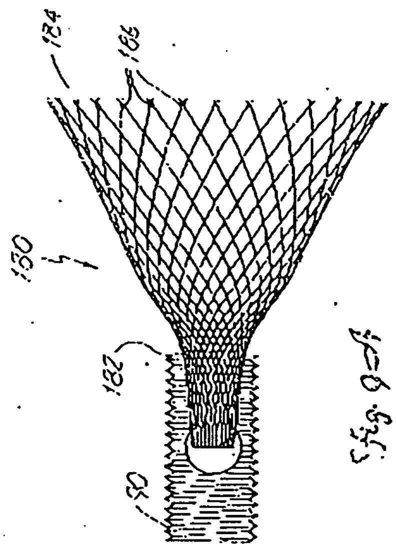

Fig. 9A

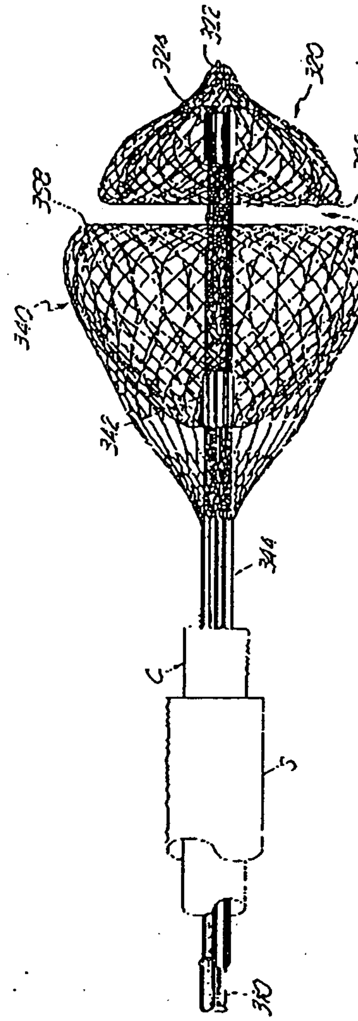

Fig. 15

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